Remarks

The Office Action dated August 24, 2009 has been received and reviewed. Claim 94 having been amended herein, claim 95 having been cancelled herein, without prejudice, and no claims having been added herein, the pending claims are claims 94 and 96-117. Reconsideration and withdrawal of the rejections are respectfully requested.

Claim 94 has been amended to incorporate the subject matter of claim 95 (now cancelled). Applicants reserve the right to prosecute the subject matter of claim 94, prior to the present amendment, in subsequent continuation and/or divisional applications.

Entry and consideration of the claim amendment are requested.

The 35 U.S.C. §112, First Paragraph, Rejection

The Examiner rejected claims 94 and 96-111 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner alleged that claim 94, reciting "a continuous hydrophobic phase comprising a mixture comprising: a hydrophobic liquid; and a hydrophobic thermoplastic elastomeric polymer," fails to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph, "since there does not appear to be a written description . . . of this mixture in the application as originally filed" (Office Action dated August 24, 2009, page 2). Applicants disagree for at least the reasons provided on pages 7 and 8 of the Amendment and Response submitted May 26, 2009, wherein Applicants cited the present specification at, for example, page 9, lines 11-15, page 10, lines 4-12, page 13, line 1 through page 15, line 7, page 19, lines 17-20, page 24, lines 8-11 and 19-26, the Examples (e.g., Examples 1-3, starting at page 27, line 26), and International Publication No. WO 97/00163 (cited at page 28, lines 7-8 and incorporated by reference at page 35, lines 7-9). Applicants submit that this is more than sufficient information to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants, without acquiescing to the present rejection and merely for the purpose of expediting prosecution of the present case, have amended claim 94 to incorporate the subject matter of claim 95, which is not subject to the present rejection.

For at least this reason, Applicants submit that claims 94 and 96-111 satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of the 35 U.S.C. § 112, first paragraph, rejection are requested.

The 35 U.S.C. §103 Rejection

The Examiner rejected claims 94, 95 and 101-117 under 35 U.S.C. §103 as being unpatentable over Cilento (EP 0 512 855) in view of Asmus (U.S. Patent No. 5,270,358) and Capelli (U.S. Patent No. 5,744,151). The Examiner rejected claims 96-100 under 35 U.S.C. §103 as being unpatentable over Cilento (EP 0 512 855) in view of Takemori et al. (U.S. Patent No. 5,075,373). These rejections are respectfully traversed.

There is no teaching or suggestion in any of the cited art, used in any combination, of a polymer composition comprising: a continuous hydrophobic phase comprising a mixture comprising: a hydrophobic liquid comprising mineral oil; and a hydrophobic thermoplastic elastomeric polymer (e.g., a styrene-isoprene-styrene block copolymer); absorbent hydrophilic microparticles dispersed within the hydrophobic liquid, wherein the hydrophilic microparticles comprise a crosslinked carboxylic acid-containing organic polymer (e.g., a copolymer of sodium acrylate and acrylic acid); and a bioactive agent having a particle size less than one micron dispersed **in** the hydrophilic microparticles, wherein the bioactive agent is selected from the group consisting of a metal oxide of silver, a metal oxide of copper, a metal oxide of zinc, and combinations thereof; wherein the polymer composition is nonadherent (i.e., display a 180° peel strength of less than 1 N/cm) and contains less than 1 wt% water based on the total weight of the composition.

Cilento teaches zinc oxide, but there is no teaching or suggestion that the zinc oxide, or any other bioactive agent, is dispersed in hydrophilic microparticles. Furthermore, there is no teaching or suggestion of how to get zinc oxide, or any other bioactive agent, dispersed in hydrophilic microparticles.

Applicants are claiming a polymer composition including a bioactive agent dispersed in hydrophilic microparticles (e.g., claim 94). Applicants direct the Examiner to numerous descriptions throughout the present specification describing, for example, "sufficiently mix[ing] to impregnate at least a portion of the insoluble bioactive agent (e.g., silver compound) into the hydrophilic particles" (e.g., page 18, lines 4-6 and 13-15) and "[s]ufficient solubility . . . is desireable such that the compounds [(e.g., silver compounds)] are dissolved into the hydrophilic polymer phase" (e.g., page 16, lines 23-25). The Examples provide further description of the having a bioactive agent dispersed in hydrophilic microparticles (e.g., claim 94).

Applicants are not simply claiming a mixture of components (hydrophilic liquid phase, hydrophobic thermoplastic elastomeric polymer, hydrophilic microparticles, and bioactive agent), whereas a mixture of components is a more appropriate characterization of the Cilento composition.

The Examiner admitted, "Cilento fails to disclose (i) that the antimicrobial agent is silver oxide and disperse in the absorbent powders and (ii) that the absorbent polyacrylate powders include a mixture a (*sic*) copolymer of sodium acrylate and acrylic acid." (Office Action dated August 24, 2009, page 3.)

Asmus is directed to a gel of swollen hydrocolloid dispersed in a pressure sensitive adhesive matrix. Although Asmus teaches the use of silver oxide, for example, as an antimicrobial agent in the gel, Asmus fails to teach or suggest **a bioactive agent dispersed in hydrophilic microparticles that are themselves dispersed in a non-adherent hydrophobic liquid (e.g., mineral oil).** Furthermore, there is no teaching or suggestion of how to get silver oxide, or any other bioactive agent, **dispersed in hydrophilic microparticles that are**

themselves dispersed in a non-adherent hydrophobic liquid (e.g., mineral oil). Thus, Asmus does not provide that which is missing from Cilento.

Capelli discloses silver-based pharmaceutical compositions (title) and "[m]edical devices utilizing a hydrocolloid absorbent polymer matrix ('hydrocolloid objects')" (column 19, lines 51-52). Applicants submit that the discussion of hydrocolloids in Capelli and the application thereof by the Examiner in the present rejection are not clear.

It is not clear if "hydrocolloid objects" in Capelli means a hydrocolloid absorbent polymer matrix, a medical device utilizing a hydrocolloid absorbent polymer matrix, or something else. Further, Capelli is not clear as to what "utilizing a hydrocolloid absorbent polymer matrix" means. It is also not clear if the Examiner's allegations reciting "hydrocolloid" (e.g., "the desirability of antimicrobial agents such as silver oxide in absorbent powders is found in Capelli" (Office Action dated August 24, 2009, page 4) and "Capelli discloses . . . that it is useful to have an antimicrobial agent present in a hyrdrocolloid [*sic*]" (Office Action dated August 24, 2009, page 4)) refer to Capelli's hydrocolloid objects, hydrocolloid material, hydrocolloid dressing, hydrocolloid absorbent polymer matrix, or something else. Applicants request that the Examiner make clear which claim language is being equated with which items in Capelli, such that Applicants have a full and fair opportunity to respond to the present rejection.

To the extent that Applicants' Representatives understand the Examiner's rejection and the Capelli disclosure, Applicants note that while Capelli discloses "[i]ncorporating an antimicrobial agent with the hydrocolloid object" (column 20, lines 3-4), Capelli provides no disclosure or suggestion of a bioactive agent dispersed in hydrophilic microparticles.

Again, Applicants are claiming a polymer composition including a bioactive agent dispersed in hydrophilic microparticles (e.g., claim 94). Applicants direct the Examiner to numerous descriptions throughout the present specification describing, for example, "sufficiently mix[ing] to impregnate at least a portion of the insoluble bioactive agent (e.g., silver compound) into the hydrophilic particles" (e.g., page 18, lines 4-6 and 13-15) and "[s]ufficient solubility . . . is desireable such that the compounds [(e.g., silver compounds)] are dissolved into the

hydrophilic polymer phase" (e.g., page 16, lines 23-25). The Examples provide further description of the having a bioactive agent dispersed in hydrophilic microparticles (e.g., claim 94).

Capelli's lack of disclosure or suggestion of a bioactive agent dispersed in hydrophilic microparticles is evident in, for example, Capelli's Example 25. Example 25 includes mixing Test Composition II, which contains the stabilized silver species (e.g., silver chloride) and PEG 600, with sodium carboxymethyl cellulose (Na-CMC, which is a hydrocolloid material) prior to blending with a polyurethane prepolymer to form a hydrocolloid dressing (e.g., a medical device which has a hydrocolloid absorbent polymer matrix (column 19, lines 48-49)). Test Composition II is described in Example 4 as a solid material at room temperature, because it must be melted (see column 22 line 42). Hence, the blending or mixing of the Test Composition II with Na-CMC in Example 25 is the mixing of two solids. No silver species will migrate into the hydrocolloid material (Na-CMC) in this case.

In direct contrast, the Examples in the present specification describe mixing hydrophilic microparticles (e.g., SALCARE SC95) with quantities of an aqueous silver nitrate solution and an aqueous sodium hydroxide solution, resulting in silver-modified hydrophilic microparticles having silver oxide incorporated therein. (*See* Specification, page 1, line 33 to page 2, line 28, page 27, lines 27-29, and page 29, lines 3-15.)

For at least these reasons, neither Asmus nor Capelli provide that which is missing from Cilento.

With regard to claims 96-100, Takemori et al. do not teach any bioactive agents, or how to get a bioactive agent, dispersed in hydrophilic microparticles. Thus, Takemori et al. do not provide that which is missing from Cilento.

Accordingly, acknowledgement of the patentability of the present claims is respectfully requested.

Summary

It is respectfully submitted that all of the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

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CERTIFICATE UNDER 37 CFR §1.8:
The undersigned hereby certifies that this paper is being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 CFR §1.6(a)(4) to the Patent and Trademark Office addressed to the Commissioner for Patents, Mail Stop **Amendment**, P.O. Box 1450, Alexandria, VA 22313-1450, on this 5th day of November 2009.

By: Todd Schenk
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